Company pipeline also located within the area restricted by EPA's action under section 404(c). No information has been provided which suggests that such maintenance has had greater impacts than expected.

Dated: March 31, 1992.

Martha G. Prothro,

Acting Assistant Administrator for Water.

[FR Doc. 92-8965 Filed 4-16-92; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

Technical Advisory Committee for Diabetes Translation and Community Control Programs: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control (CDC) announces the following committee meeting.

Name: Technical Advisory Committee for Diabetes Translation and Community Control Programs.

Time and Date: 8 a.m.-4:30 p.m., Tuesday, May 19, 1992.

Place: Ramada Renaissance Hotel Atlanta Airport, 4736 Best Road, College Park, Georgia 30337. (Exit Riverdale Road off I-85.)

Status: Open to the public, limited only by the space available.

Purpose: This committee is charged with advising the Director, CDC, regarding priorities and feasible goals for translation activities and community control programs designed to reduce risk factors, morbidity, and mortality associated with diabetes and its complications. The Committee advises regarding policies, strategies, goals and objectives, and priorities; identifies research advances and technologies ready for translation into widespread community practice; recommends public health strategies to be implemented through community interventions; advises on operational research and outcome evaluation methodologies; identifies research issues for further clinical investigation; and advises regarding the coordination of programs with Federal, voluntary, and private resources involved in the provision of services to people with diabetes.

Matters to be Discussed: The Committee will continue to discuss specific objectives related to translation for Technical Advisory Committee for Diabetes Translation and Community Control Programs. In addition, the Committee will discuss issues related to current research and science that is ready for translation into communitywide practice. Division of Diabetes Translation staff will provide updates on diabetes control activities and programs currently operational within and outside of the Division.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Frederick C. Murphy, Program Analyst, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, CDC, 1600 Clifton Road, NE, (K-10), Atlanta, Georgia 30333, telephone 404/488-5005 or FTS 236-5005.

Dated: April 10, 1992.

Elvin Hilyer,

Associate Director for Policy Coordination Centers for Disease Control.

[FR Doc. 92-8912 Filed 4-16-92; 8:45 am]

BILLING CODE 4160-18-M

National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Mental Health Statistics: Meeting

Pursuant to Public Law 92-463, the National Center for Health Statistics (NCHS), Centers for Disease Control, announces the following committee meeting.

Name: NCVHS Subcommittee on Mental Health Statistics.

Time and Date: 9:30 a.m.-4 p.m., May 22, 1992.

Place: Room 337A-339A, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open.

Purpose: The subcommittee will continue deliberations initiated at previous meetings regarding the collection and analysis of institutional and person oriented longitudinal data on children and youth with mental disorders. The subcommittee will also review recent developments in the area of disability statistics particularly as they relate to proposed activities at NCHS and the National Academy of Sciences.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone number 301/436-7050 or FTS 436-7070.

Dated: April 10, 1992.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 92-8911 Filed 4-16-92; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 91E-0476]

Determination of Regulatory Review Period for Purposes of Patent Extension; Dermatop®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Dermatop® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joel Sparks, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Dermatop®. Dermatop® (prednicarbate) is indicated for the relief of the inflammatory and

pruritic manifestations of corticosteroid-responsive dermatoses. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Dermatop® (U.S. Patent No. 4,242,334) from Hoechst Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated January 30, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Dermatop® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Dermatop® is 3,532 days. Of this time, 1,450 days occurred during the testing phase of the regulatory review period, while 2,082 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The Date an Exemption Under Section 505(i) of the Federal Food, Drug, and Cosmetic Act Became Effective

January 21, 1982. The applicant claims January 22, 1982, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 21, 1982, which was 30 days after FDA receipt of the IND.

2. The Date the Application Was Initially Submitted With Respect to the Human Drug Product Under Section 505(b) of the Federal Food, Drug, and Cosmetic Act

January 10, 1986. FDA has verified the applicant's claim that the new drug application (NDA) for Dermatop® (NDA 19-568) was submitted on January 10, 1986.

3. The Date the Application Was Approved

September 23, 1991. FDA has verified the applicant's claim that NDA 19-568 was approved on September 23, 1991.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 2 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 16, 1992, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 14, 1992, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 7, 1992.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 92-8872 Filed 4-16-92; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

National Cancer Institute; Meeting of the National Cancer Institute Frederick Cancer Research and Development Center Advisory Committee

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the National Cancer Institute Frederick Cancer Research and Development Center Advisory Committee, June 11 and 12, 1992, Building 549, Executive Board Room, NCI Frederick Cancer Research and Development Center, Frederick, Maryland.

This meeting will be open to the public on June 11 from 8:30 a.m. to approximately 9:30 a.m. to discuss administrative matters such as future meetings, budget and informational items related to the operation of the NCI Frederick Cancer Research and Development Center. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92-463, the meeting will be closed to the public on June 11 from approximately 9:30 a.m. to adjournment on June 12 for a discussion of the previous site visit reviews of the AIDS Vaccine Program under contract with Program Resources, Inc. and the Laboratory of Chromosome Biology under contract with Advanced BioScience Laboratories, Inc. During the closed portion, a site visit review of the Molecular Mechanisms of Carcinogenesis Laboratory under contract with ABL-Basic Research Program will be conducted.

These discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contractor, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Carole Frank, Committee Management Officer, National Cancer Institute, Building 31, room 10A06, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892, Tel. (301) 496-5708, will provide a summary of the meeting and a roster of committee members upon request.

Dr. Cedric W. Long, Executive Secretary, Frederick Cancer Research and Development Center Advisory Committee, National Cancer Institute Frederick Cancer Research and Development Center, P.O. Box B, Frederick, Maryland 21702-1201, Tel. (301) 846-1108, will furnish substantive program information upon request.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower, 93.399, Cancer Control.)

Dated: April 8, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 92-8881 Filed 4-16-92; 8:45 am]

BILLING CODE 4140-01-M

National Cancer Institute; Meetings of the National Cancer Advisory Board and its Subcommittees

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the National Cancer Advisory Board, National Cancer Institute, and its Subcommittees on May 5-6, 1992. The full Board will meet in Conference Room 10, 6th Floor, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. Meetings of the Subcommittees of the Board will be held at the times and places listed below. Except as noted below, the meetings of the Board and its